SUMMARY MINUTES

OF THE

OPHTHALMIC DEVICES PANEL MEETING

ONE HUNDRED AND FIRST MEETING

July 20, 2001

OPEN SESSION

Main Conference Room
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD

OPHTHALMIC DEVICES PANEL MEETING

July 20, 2001

PANEL PARTICIPANTS

Joel Sugar, M.D.	Chair
Michael R. Grimmett, M.D.	Voting Member
Janice M. Jurkus, O.D.	Voting Member*
Alice Y. Matoba, M.D.	Voting Member*
Jose S. Pulido, M.D.	Voting Member
Jayne S. Weiss, M.D.	Voting Member
Karen Bandeen-Roche, Ph.D.	Consultant, deputized to vote
Timothy B. Edrington, O.D.	Consultant, deputized to vote
Timothy T. McMahon, O.D.	Consultant, deputized to vote
Barry A. Weissman, O.D., Ph.D.	Consultant, deputized to vote
Karla S. Zadnik, O.D., Ph.D.	Consultant, deputized to vote
Marcia S. Yaross, Ph.D.	Industry Representative

*Primary Reviewer for PMA P010019

FOOD AND DRUG ADMINISTRATION PARTICIPANTS

Sara M. Thornton	Panel Executive Secretary
A. Ralph Rosenthal, M.D.	Director, Division of Ophthalmic Devices
Everette T. Beers, Ph.D.	Acting Chief Diagnostic and Surgical Devices Branch
James F. Saviola, O.D.	Chief, Vitreoretinal and Extraocular Devices Branch Acting Chief, Ear, Nose and Throat Devices Branch

Donna R. Lochner	Chief Intraocular & Corneal Implants Branch
Bernard P. Lepri, O.D., M.S., M.Ed.	Optometrist Vitreoretinal & Extraocular Devices Branch
Gene Hilmantel, O.D., M.S.	Optometrist Vitreoretinal & Extraocular Devices Branch
Myra K. Smith, M.S.	Microbiologist Team Leader P010019 Vitreoretinal and Extraocular Devices Branch
Karen F. Warburton, M.H.S.	Microbiologist Vitreoretinal and Extraocular Devices Branch

SPONSOR REPRESENTATIVES

Alicia M. Plesnarski, RAC
Senior Specialist, CIBA Vision Global Regulatory Affairs

John McNally, O.D., F.A.A.O.
Head, CIBA Vision Continuous Wear Projects

Scott R. Robirds, O.D., F.A.A.O.
Head, CIBA Vision Global Clinical Affairs

Supporting Team—

Curtis D. McKenney, O.D. (clinical data)
Senior Clinical Project Manager, CIBA Vision Research Clinic

Gary Cutter, Ph.D. (statistical analysis)
Phthagoras, Inc.

Stuart Heap (sponsor closing remarks)
President, CIBA Vision Lens Business Unit

OPEN SESSION—July 20, 2001

Joel Sugar, M.D., Panel Chair, called the meeting to order at 9:30 a.m. **Sara M. Thornton, Panel Executive Secretary,** noted that this session was the 101st meeting of the Ophthalmic Devices Panel, and that the next panel session was scheduled for September 21, 2001. She introduced four new panel consultants: Timothy B. Edrington, O.D., Timothy T. McMahon, O.D., Barry A. Weissman, O.D., Ph.D., and Karla S. Zadnik, O.D., Ph.D. Ms. Thornton asked the other panel members to introduce themselves and noted that Consumer Representative Lynn Morris was unable to attend because of a recent injury. Ms. Thornton read the conflict of interest statement, noting that Karla S. Zadnik, O.D., Ph.D., had declared an interest in a firm potentially affected by the day's deliberations but her full participation would be allowed. Matters concerning Karen Bandeen-Roche, Ph.D., Timothy B. Edrington, O.D., Timothy T. McMahon, O.D., Barry A. Weissman, O.D., Ph.D., and Karla S. Zadnik, O.D., Ph.D., had been considered but deemed unrelated and their full participation allowed. She also read a deputization to voting status for Karen Bandeen-Roche, Ph.D., Timothy B. Edrington, O.D., Timothy T. McMahon, O.D., Barry A. Weissman, O.D., Ph.D., and Karla S. Zadnik, O.D., Ph.D.

OPEN PUBLIC HEARING

Professor Brien A. Holden, Ph.D., Director of the Cooperative Research Centre for Eye Research & Technology of Sydney, Australia, discussed microbial keratitis (MK) and vision loss with extended or continuous wear lenses. He looked at the history of extended wear

(EW), presenting study results on the incidence of MK with a variety of lens type and showing data that the risk of MK is five times greater with EW lenses of conventional low oxygen permeability (Dk) than with daily wear lenses. Dr. Holden also compared serious adverse events with contact lenses to those with LASIK, stating that MK is by far the most frequent and worrisome serious adverse event with contact lenses. After explaining risk factors for MK with EW of low Dk soft lenses, he presented clinical studies done at his institute on incidence of MK that compared low and high Dk lenses, with results highly favorable to high DK lenses. Pooled data from other high Dk clinical studies found no incidence of MK in high DK lenses in an equivalent of 2986 person/years. He noted that experience in the global marketplace showed a very low rate of MK in high Dk soft lenses and a zero rate of loss of two lines or more of best corrected visual acuity (BCVA). Dr. Holden stated that continued postmarket surveillance to determine incidence of MK and visual outcomes is key. He added that the world needs a gold standard study of the prevalence and relative risk of MK with EW of high Dk soft lenses, and that he and his colleagues currently are undertaking a global collaboration to assess what is needed to conduct a series of case-control studies.

Associate Professor Deborah F. Sweeney, Ph.D., Executive Director of the Cooperative Research Centre for Eye Research & Technology, discussed attitudes toward continuous (extended) wear with silicone hydrogels, showing statistics on EW as the preferred mode of wear. She showed data from patient surveys indicating that patients want comfort and convenience and that those wearing EW lenses have high overall satisfaction levels. Clinical

studies at the Centre show that a large majority of EW patients wear their lenses for 28-30 nights without removing them and are enthusiastic about the convenience and freedom from spectacles.

Dr. D. James Kerr, of the West Vision Center of Saskatoon, Saskatchewan, Canada, discussed his positive clinical experience with the CIBA EW lens during the Canadian clinical trial and the positive experiences of patients in his practice who have used the lens. He listed minor complications that have occurred, such as contact lens-induced acute red eye, which have resolved well. Dr. Kerr stated that patient acceptance and demand for the lens have been high. He discussed risk management of the lens and compared it to that for refractive surgery, noting that complications from refractive surgery can be permanent and irreversible. Referrals for refractive surgery are also down in his practice. He concluded that this lens has revolutionized his practice, and he expressed regret that it is not yet available in the United States.

OPEN COMMITTEE DISCUSSION

Division and Branch Updates

A. Ralph Rosenthal, M.D., Director of the Division of Ophthalmic Devices, told the panel that Nancy Brogdon has been promoted to Director of the Division of Reproductive, Abdominal and Radiological Devices, and that David Whipple has been appointed Deputy Director of the Division of Ophthalmic and Ear, Nose and Throat Devices.

Everette T. Beers, Ph.D., Acting Chief of the Diagnostic and Surgical Devices Branch, gave the branch update, stating that there have been no personnel changes. He listed one PMA approval, for the VISX LASIK for hyperopic astigmatism of +5.0D sphere and +3.0D

cylinder. In the 510k area, the B&L Proview Eye Pressure Monitor, an over-the-counter device for home use, was approved in June 2001. He added that keratome LASIK guidance is now on the CDRH website. It states that keratomes may now use LASIK in their promotion, a change from before. Also Wave Front Analysis Autorefractometers (aberrometers) have been declared exempt with limitations, meaning that sponsors do not have to submit premarket notification to FDA but that exempt aberrometers must carry a warning that safety and effectiveness have not been established for determining treatments for higher order aberrations of the eye. Dr. Beers also noted that there is a LASIK website (http://www.fda.gov/cdrh/lasik/) and that all consumer calls should be forwarded to the Office of Health and Industry Programs in the Division of Small Manufacturers Assistance via email at DSMA@CDRH.FDA.GOV.

Ms. Donna R. Lochner, Chief of the Intraocular and Corneal Implants Branch (ICIB), gave the branch update. She reported that PMA P000026 for Staar Surgical, Co.'s AquaFlow Collagen Glaucoma Drainage Device, which was reviewed by the panel in November 2000, was approved on July 12, 2001. Pharmacia's PMA P990080 CeeOn Edge Foldable UV-absorbing PC IOL, which was not brought to panel, was approved on April 5, 2001. Anika Therapeutics, Inc. has also received approval on April 18, 2001 for a licensing PMA P000046 in which Bausch and Lomb provided reference rights to P810025 Amvisc sodium hyaluronate viscoelastic. She stated that Anika has approval to distribute and manufacture the Amvisc sodium hyaluronate under their label, but has instead received approval for Staar Surgical Company to distribute the product as Staarvisc II sodium hyaluronate.

James F. Saviola, O.D., Chief of the Vitreoretinal and Extraocular Devices Branch, gave the branch update, in which he referred the panel to a notice on the FDA website regarding web distribution of contact lenses. He also listed three 510ks cleared for orthokeratology: K010109 Paragon Fluroperm151-OK, which was cleared on February 28, 2001 and whose labeling references a 60 OK study, and K003932 for Polymer Tech Boston EO and K003933 for Polymer Tech Boston Equalens II, both of which were approved on February 16, 2001 and whose labeling refers to Contex's clinical study. He noted that there are now a total of six daily wear orthokeratology lenses cleared.

Dr. Saviola also stated that two more lens care products have received a no-rub clearance for lenses replaced every 30 days or less: Allergan Complete Multipurpose solution and CibaVision's AO Sept One-Care peroxide solution. Wording remains in the labeling to advise users that additional products or procedures such as rubbing their lenses may be recommended by the eye-care practitioner.

The branch has approved one PMA, for the Vistakon (lenefilcon a) soft hydrophilic contact lens indicated for daily and extended wear up to seven days, on February 16, 2001.

Questions from the panel concerned patient age indications for IOLs. Ms. Lochner explained that the agency is preparing a meta-analysis of the literature on this subject in hopes of publication so that sponsors could use this article to support a lower age indication. There was also an inquiry regarding future panel review of orthokeratology lenses. Dr. Saviola stated that the applications for overnight wear orthokeratology lenses will be considered as panel track

PMA P010019

Sponsor Presentation

Alicia M. Plesnarski, RAC, Senior Specialist, CIBA Vision Global Regulatory Affair, provided background about the sponsoring company, CIBA Vision Corporation, and the device, the SEE3 or Focus Night and Day soft contact lens indicated for correction of ametropia in phakic or aphakic persons with up to 1.5 D of astigmatism for up to 30 nights of continuous wear. It is a Class III extended wear (EW) soft contact lens of high oxygen permeability (Dk) that has been cleared for daily use in the United States and in Europe as a 30-day EW lens. She stated that a comprehensive range of nonclinical tests supported the safety of the lens for its intended use. Ms. Plesnarski also introduced the rest of the sponsor team.

John J. McNally, O.D., F.A.A.O., Head, CIBA Vision Continuous Wear Projects, described the lens material properties and performance, which produced superior results in the areas of low overnight corneal swelling, lack of bacterial colonization, and improved lens cleanliness. He summarized the international market experience since the EW lens was introduced in 1999 as highly positive, with the lens proving a desirable vision correction alternative in terms of convenience, less lens dryness and redness, and ability to correct high refractive errors.

Dr. McNally explained the design and results of the safety study, which compared the SEE3 lens, worn up to one month continuously before replacement, to the Acuvue control lens, worn up to one week continuously before replacement. The study was a one-year, open-label,

multicenter, randomized controlled trial looking at wearing schedule and replacement frequency differences. At the time of the study there was a single base curve for the experimental lens. The primary safety endpoint was infiltrates of grade 3 or greater or infiltrates with fluorescein staining as a surrogate for MK. Primary effectiveness endpoints were visual acuity (VA) within two lines of the dispensing VA and wearing time achieved. Dr. McNally explained the noninferiority statistical design, sample size, and power used in the study.

Dr. McNally discussed study results in terms of enrollment and accountability, discontinuations, primary safety endpoint and adverse events, primary effectiveness endpoints, and dryness symptoms. The subject groups were similar, except that 20 SEE3 lenses were not dispensed because of fitting problems. Demographics showed both groups to be representative of the contact lens population, and subject accountability was high. Discontinuations because of discomfort with the lens or positive biomicroscopy were higher for the SEE3 group than for control, with the majority of discontinuations in the SEE3 group occurring in the first month because of fitting discomfort. Anticipating reviewers' questions, Dr. McNally stated that SEE3 discomfort discontinuations showed no correlation to keratometry or refractive error. He also examined biomicroscopy discontinuations for both groups and found no significant differences.

Dr. McNally stated that results in terms of primary safety endpoints were not statistically different for the two groups in terms of infiltrate rate or the estimated annualized infiltrate rate. The SEE3 lens was not inferior to the control lens within an equivalence margin and produced no loss of best corrected visual acuity (BCVA). Development of infiltrates showed no correlation to

refractive error, keratometry, or fit. Infiltrates were paracentral and limbal; there was a higher risk for patients with a history of infiltrates and a higher trend in smokers.

Dr. McNally discussed rates for all adverse events. He defined serious, significant, and nonsignficant adverse events and showed rates for each as well as cumulative rates. There was no difference in incidence of adverse events between the two groups; there were no cases of microbial keratitis and no loss of BCVA. Dr. McNally also discussed rates of contact lens induced papillary conjunctivitis (CLPC), noting that while rates were higher for the SEE3 lens, a number of these cases came from one investigator. There was no correlation to surface deposits, fit, or power, although there appeared to be a higher risk if the patient had a prior history of CLPC.

Primary effectiveness endpoints included vision results and wearing time. Dr. McNally stated that there was no loss of BCVA within two lines and visual acuity (VA) with contact lenses remained within two lines of baseline VA for 98% of patients. Prescribed wearing time (based on investigator judgment) showed over 90% of patients were prescribed a 30-day wearing schedule, with no subjects permanently prescribed less than the full indication, although prescribed wearing time was temporarily reduced to manage signs or symptoms. Reported wearing time results were based on the period between overnight removals, which could be done for symptoms or for lifestyle requirements. The majority showed that more than half of the subjects wore the lenses for 22 to 31 nights, with more than 80% wearing them for more than seven consecutive nights. Anticipating reviewer questions, Dr. McNally stated that there was no

correlation between consecutive months of 30 nights' wear prior to an adverse event or between number of consecutive days of wear at the time of an event. Reasons for shorter wearing time included unscheduled overnight removals for rest, irritation, or allergy, or temporary daytime removals for cleaning lenses, irritation, or dryness.

Dr. McNally presented data showing that there were fewer symptoms of dryness and less subjective dryness upon awakening in the SEE 3 group than in the control group, as well as statistically fewer unscheduled overnight removals for dryness. He suggested that these data supported an indication that the lens "may reduce dryness symptoms that are present with regular hydrogel lenses."

Scott R. Robirds, O.D., F.A.A.O., Head, CIBA Vision Global Clinical Affairs, read the product description and proposed indications for use. He suggested revised wording for the warning section on the risk of ulcerative keratitis and stated that because 30-night EW is an important departure from the current six-night EW indication, changes should be made to the current EW labeling based on data from the pivotal study. Mr. Robirds also described the proposed postapproval evaluation, explaining the study design and rationale for an observational study of 2000 SEE 3 wearers (30 new) at 100-200 sites of one year duration to look at microbial keratitis, and loss of BVA of two lines or greater after resolution of MK or other inflammation.

Panel questions to the sponsors included statistical issues, the proposed range versus available data on powers tested, average wearing times, fit and visual acuity, and whether there

might be a subgroup of patients who do not tolerate the new material well and show signs of increased burning and awareness.

FDA Presentation

PMA Team Leader, Myra K. Smith introduced the FDA review team and Dr. Bernard P. Lepri, the clinical reviewer for the application. Dr. Lepri discussed the history of EW contact lenses, noting the primary complication of corneal ulcers and the relationship of hypoxia to infiltrate and ulcer development. He stated that the sponsors believe that the SEE3 lens addresses these issues because of its high Dk (oxygen permeability). Dr. Lepri also noted the difference in the range of lens powers tested in the clinical trial as compared to those available, saying that FDA policy determines the appropriate range of power approval for EW lenses based upon the effects of lens thickness on lens permeability. The sponsor will have to demonstrate these data to FDA before final approval.

Dr. Lepri explained that sponsors designed the clinical trial in consultation with FDA for determination of noninferiority to the control device. The primary endpoint rate was based on an Acuvue 8.6% rate of infiltrate as a surrogate for MK. He explained that this surrogate endpoint was chosen because of its effects upon sample size and because infiltrate development usually precedes ulcer development and provides an estimate of safety upon which a postapproval study would be conducted to attempt to determine the true rate of MK. Endpoint goals were based on the fact that not everyone would or should wear this lens for 30 days, and this study was designed to determine the proportion of patients that could safely wear this type of lens for 30 days.

Dr. Lepri presented the study findings, which showed that an infiltrate event in one eye carries a six times greater risk of a second event in the same or fellow eye as compared to having a first event. The study also found that SEE3 infiltrate endpoints occurred earlier in the study than did Acuvue endpoints, although standard lens labeling generally states that the incidence of ulcers increases with the length of wear time. Dr. Lepri asked the panel to address whether this general warning about ulcers and wear time should be retained or replaced with the study findings. The study also found that SEE3 events tended to occur early on, when patients are most closely monitored, as opposed to the control group. There were no differences in gender or age among those developing infiltrates, and many had worn extended wear lenses prior to study participation.

Dr. Lepri noted that the average wear time in this study for all completed patients was 27 days, which was achieved by 67% of the dispensed cohort. Of those who discontinued, only a small percent were discontinued for positive biomicroscopy findings. The majority were discontinued for lens fit, discomfort, acuity problems, or loss to follow-up.

Dr. Lepri also reported on subjective findings reported in the patient diaries, which showed that SEE3 patients had fewer complaints of dryness than the Acuvue patients at a statistically significant level. He asked the panel to address the clinical significance of this finding and to consider whether a labeling claim for reduced dryness with the lens should be allowed. Dr. Lepri then read the FDA questions for panel review.

Committee Deliberations

Primary Panel Reviews

Janice M. Jurkus, O.D., M.B.A., gave the first panel review. She focused on the percentage of not dispensed lenses and discontinued patients, citing discomfort, lens fit, and positive biomicroscopy as common reasons for discontinuation, all of which showed higher percentages for the test than the control group. She noted the sponsors' suggestion that the limitation on one base curve might be the cause, which is supported by the fact that the majority of discontinuations occurred in the first week of wear and the remainder within the first month. Dr. Jurkus noted that the sponsor is requesting approval for an additional steeper base curve, but no testing was done with this design. She recommended that fitting instructions should be addressed in the labeling.

On safety results, Dr. Jurkus noted that the SEE3 lens is noninferior to the Acuvue lens with regard to the primary safety endpoint of corneal infiltrates. She observed that the timing of infiltrate appearance was earlier in the study for the SEE3 group and again might be related to less than optimal lens fit, suggesting that fitting analysis appears to be critical with this lens. Dr. Jurkus thought it interesting that repeat event analysis indicated a greater risk of infiltrate appearance for patients with a prior episode than for the first time appearance and that timing of infiltrate appearance was earlier in the study for the SEE3 group, both of which should be noted in the labeling. Dr. Jurkus emphasized that it is critical to stress patient awareness of symptoms and appropriate action for all EW lenses. She found other adverse event rates to be similar for the

two groups, although contact lens-associated papillary conjunctivitis (CLPC) was higher with the SEE3 group. She recommended practitioners should be made aware of the CLPC data.

Dr. Jurkus stated that from a clinical standpoint she thought there was not a big difference between the SEE3 group and control in terms of dryness. Efficacy results in terms of vision outcome and percentage use of continuous wear were very good. In terms of safety, she thought the lens does no significant harm as far as now known. The infiltrate rate is the same as that in reported studies, and a postmarketing study can answer the question of microbial keratitis. Labeling revisions can address other issues and limitations. In her clinical opinion, complications associated with this new modality fall somewhere between that of daily contact lens wear and refractive surgery. Problems that occurred generally did so early in the lens wearing experience, which indicates the need for careful fitting, follow-up, and patient education. The postmarket approval study is extremely important to monitor the use of this lens in the general population.

Alice Matoba, M.D., gave the second panel review. She stated that problems with unacceptable acuity due to distortion of optics secondary to problems with packaging or problems with discomfort due to limited number of base curves have been addressed to her satisfaction. She said that she was initially troubled by the fact that only 67% of the SEE 3 group achieved 30-day wear, which suggested that this study does not really compare the safety of the SEE3 lens worn 30 days to the Acuvue Lens worn seven days. However, she was reassured to see that average wear approaches 25-27 days, so she was no longer bothered by this apparent discrepancy. Safety concerns raised in her written review about the nature of the infiltrates seen

had largely been addressed by sponsors. In answering the FDA review questions, Dr. Matoba stated that the data provided reasonable assurance of safety and effectiveness, although she wanted the indication for reduced dryness reworded. She had no problem with a 30 day maximum amount of wear as stated in the labeling, but urged that the statistically significant incidence of GPC (CLPC) as shown in the study should be included. The labeling should state also that there is a greatly increased risk of a second infiltrate after the first infiltrate occurs. Dr. Matoba urged a prospective postapproval study within the U.S. population to gather information on the incidence of MK, with study subjects wearing the lenses as close to 30 days as possible. She had no recommendation concerning the use of foreign data in the postapproval study.

Panel Discussion of P010019

There was considerable panel discussion of how the incidence of MK could be established in the broader population. Panel members sounded a cautionary note that the postmarket study as proposed will not answer the question of MK incidence and that perhaps that issue cannot be answered until the lenses are in the hands of practitioners. Another panel member asked whether aphakic patients should be included, given their possibly higher rate of infection, although it was noted that this is a standard part of lens labeling. The panel discussion focused on the higher incidence of GPC in the SEE3 group, and members agreed that the sponsor should reflect this issue in the labeling data.

FDA Questions

1) Do the data presented in PMA P010019 provide reasonable assurance of safety and effectiveness for the proposed indication for use?

The consensus of the panel was that the PMA does provide reasonable assurance of safety and effectiveness, based on the assurance that most subjects wore the lens for an average of 25-27 days and that the nature and rate of infiltrates observed were as described by sponsors.

2) Does the panel recommend any modification of the proposed indication statement?

The panel recommended removing the fourth bullet of the indication relating to reduced dryness symptoms. After a suggestion to remove the word “aphakic” from the first bullet of the indication; it was subsequently decided to leave the word “aphakic” in the indications but to add a warning that information on performance with aphakia is not yet available.

3) Please discuss the merits of including the maximum 30-day time period in the indication statement. Does the panel recommend that it be included in other sections of the product labeling rather than the indication section?

Although the panel acknowledged the FDA’s concern about possible future data from the postmarket study that might force a revision of the labeling, the panel recommended leaving the maximum 30-day time period in the indication statement and elsewhere.

4) Does the panel have any specific recommendations for the proposed product labeling in terms of warnings, precautions, clinical data outcomes, or practitioner- or patient-directed labeling? There was not overwhelming support for patient-directed package labeling, with some arguing that this lens is not so different from seven-day wear lenses as to warrant special consideration. Others disagreed, saying that the history of complications with EW lenses suggests that special labeling for all new EW lenses should warn patients that this device is available by prescription only and that they should see practitioners in the event of pain, redness, discharge, or problems.

The panel had a number of recommendations on proposed product labeling, which should:

-- mention that infiltrates occurred sooner with this lens than with control.

-- present the specific data showing that patients who had previously had GPC had a greater chance of having GPC again, that the rate of GPC with the SEE3 lens was higher than that with the Acuvue lens, and that the onset of GPC was earlier with the SEE3 lens than with Acuvue.

--report the aggregate and annual rate data for infiltrates.

--caution practitioners that those patients who develop an infiltrate have a six-fold higher chance of developing another.

--note that use with aphakics was not studied and that the new base curve was not a part of the study.

--highlight that the incidence of long-term ulcerative keratitis has not been determined, that there are ongoing postmarketing studies, and that adverse events should be reported to sponsors.

--present wearing time data so that patients can see that the percentage of patients wearing the lens for 30 consecutive days.

After discussion, the sense of the panel was that no additional recommendation on fitting the lens was necessary. The sponsors may include data on reduced dryness with the SEE3 lens, but that indication should be deleted. The summary of safety and efficacy should include alternative modalities such as LASIK and daily wear use, but they do not have to be listed in the labeling.

5) Does the panel recommend that the sponsor conduct a prospective postapproval study within the U.S. population to gather information on the incidence of microbial keratitis?

The panel recommended that there should be a postapproval study and noted that industry is still looking at what the guidelines should be.

6) In consideration of potential differences in the standard of care and device usage patterns outside of the U.S., does the panel have any recommendation concerning the use of foreign data in the postapproval study?

Industry Representative Marcia Yaross observed that there are regulations already governing the use of foreign data. The panel agreed to leave determination of which data sets to include to industry and the FDA.

Open Public Hearing

Brien Holden of the Cooperative Research Centre for Eye Research and Technology stated that anything that can be done for aphakics to have lenses should be encouraged, especially the use of high Dk lenses. He stated that a higher rate of CLPC than that seen in the control group is common for low water lens and that the rate of CLPC with SEE3 should not be seen as worrisome. He suggested that the infiltrative responses seen with SEE3 may be a response to bad fit, based on the one available base curve, and he stressed that studies are continuing on ulcerative keratitis. Dr. Holden urged that dryness information be included in the labeling because this is an issue for many contact lens wearers.

FDA Closing Comments

FDA representatives had no additional remarks.

Sponsor Closing Comments

Stuart Heap, President, CIBA Vision Lens Business Unit, thanked the panel. He listed several reasons for research and development in EW, including giving the consumer more options and providing greater safety and convenience.

Panel Vote

Executive Secretary Sara Thornton read the voting instructions and options. A motion was made and seconded to recommend the PMA as approvable subject to the following conditions:

1. The statement regarding “less dryness complaints” should be eliminated from the indications for use statement. (This condition passed unanimously).

2. The word “aphakia” should be left in the indications statement, but the warning section should state that there is no information about use with aphakes. (This condition passed with one abstention).

3. Regarding GPC, the labeling should note that there is (1) a higher rate of GPC for patients with a history of prior GPC; (2) a higher rate of GPC with the SEE3 lens as compared with the Acuvue lens regardless of whether there was any prior history of GPC; and, the onset of GPC occurs earlier with the SEE3 lens as compared to the Acuvue lens. (This condition passed unanimously.)

4. The labeling should indicate that the timing of infiltrates occurred sooner with the SEE3 lens than with the Acuvue lens. (This condition carried by a vote of seven to three.)

5. Labeling should state that once an infiltrate has occurred, there is a six time higher rate for the second event and more caution is required. (This condition passed unanimously.)

6. Labeling should state the aggregate infiltrate rate (6 % for SEE3 and 3% for Acuvue). (This condition passed unanimously.)

7. Labeling should state that the risk of MK in this lens has not been established, that postmarket studies are underway, and that serious adverse events such as microbial keratitis should be reported to the sponsors. (This condition passed unanimously.)

8. The panel recommended a postmarket study.

The vote to recommend the PMA as approvable subject to the above conditions was carried unanimously.

Panel Chair Dr. Sugar adjourned the Open Session at 3:15 p.m.

I certify that I attended the Open Session of the Ophthalmic Devices Advisory Panel Meeting on July 20, 2001, and that this summary accurately reflects what transpired.

_____

Sara M. Thornton
Executive Secretary

I approve the minutes of this meeting
as recorded in this summary.

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Joel Sugar, M.D.
Chair

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